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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,341

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

11/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,341	Applicant(s) TROTTER ET AL.	
	Examiner TAMTHOM N. TRUONG	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 6-17 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/12/06 + 7/10/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of Group I in the reply filed on 8-20-09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-17 and 20-22 are withdrawn as being drawn to the non-elected subject matter.

Claims 1-5, 18 and 19 are pending.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-5, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 1 recites "z" as a "single or double bond". However, when "z" is a single bond, the ring carbon (at 2-position) has an incomplete valence.
- b. Claim 5 recites the limitation of "R¹ is absent when z is a double bond" which does not seem logical when R⁵ is =O because then the ring carbon would have an extra valence if z is also a double bond.

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c. Claim 18 is rejected for reciting the limitation "hydrate" in a pharmaceutical formulation. There is insufficient antecedent basis for this limitation in the claim because claim 1 does not recite "hydrate".

Claim Rejections - 35 USC § 102

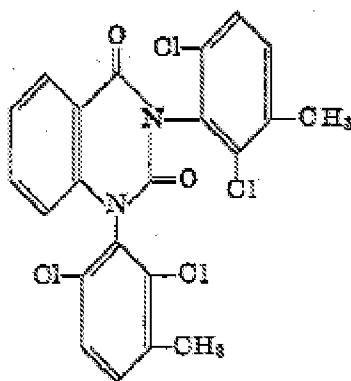
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the following references:

a. **Juby** (US 3,294,813): In column 10, Juby discloses the compound of *1,3-bis(2,6-dichloro-3-methylphenyl)-2,4-quinazolinedione* with the following structure:



Said compound reads on the instant quinazolinone formula with the following substituents as recited in claims 1, 18 and 19:

- i. A is a phenyl ring substituted with halogens and an alkyl group;
- ii. R^1 is $(CR^aR^b)_nR^{40}$; $n = 0$;
- iii. R^{40} is an aryl group substituted with halogens and an alkyl group;
- iv. R^5 is an =O group;
- v. R^2 and R^8 - R^{10} are hydrogen.

b. **Lowe, III** (US 4,797,403): In column 8, Lowe discloses Example 14 with the compound of *1-(3-Carboxyphenyl)-3-benzylquinazoline-1H,3H-2,4-dione*, and also in column 9, Example 15 with the compound of *1-(3-N-Methylcarboxamidophenyl)-3-benzylquinazoline-1H,3H-2,4-dione*. Both compounds read on the instant quinazolinone formula with the following substituents as recited in claims 1-3, 18 and 19:

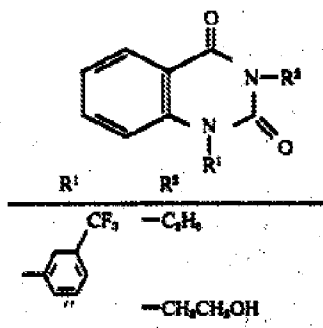
- i. A is a phenyl ring substituted with $(CR^iR^j)_rC(O)OR^{46}$ wherein R^{46} is hydrogen, or the phenyl ring is substituted with $(CR^iR^j)_rC(O)N(R^{47}R^{48})$ wherein R^{47} is hydrogen, and R^{48} is a methyl group;
- ii. R^1 is $(CR^aR^b)_nR^{40}$; $n = 1$;
- iii. R^{40} is an aryl group;
- iv. R^5 is an =O group;
- v. R^2 and R^8 - R^{10} are hydrogen.

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c. **Connor et. al.** (US 5,155,110): In column 30, Connor discloses Example 45 with the compound *1-(2,6-Dichloro-3-methylphenyl)-3-methoxy-2,4-(1H,3H)quinazolinedione*. Said compound reads on the instant quinazolinone formula with the following substituents as recited in claims 1, 18 and 19:

- i. A is a phenyl ring substituted with halogens and an alkyl group;
- ii. R^1 is $(CR^aR^b)_nOR^{40}$; $n = 0$;
- iii. R^{40} is an alkyl group;
- iv. R^5 is an =O group;
- v. R^2 and R^8 - R^{10} are hydrogen.

d. **Noda et. al.** (US 4,016,166): In columns 9 and 10, the compound having the following structure:



reads on the instant quinazolinone formula with the following substituents as recited in claims 1-3, 18 and 19:

- i. A is a phenyl ring substituted with $(CR^iR^j)_rR^{46}$; $r = 1$;
- ii. R^i , R^j and R^{46} are fluoro;
- iii. R^1 is $(CR^aR^b)_nOR^{40}$; $n = 1$;

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iv. R^{40} is hydrogen or an alkyl group;

v. R^5 is an =O group;

vi. R^2 and R^8 - R^{10} are hydrogen.

e. **Yabuuchi et. al.** (DE 2,120,663 – cited on the IDS): On page 2, Yabuuchi et. al. discloses the compound of *1-(3'-Fluophenyl)-2,4(1H, 3H)-chinazolin-6-one* which reads on the instant quinazolinone formula with the following substituents as recited in claims 1-4, 18 and 19:

i. A is a phenyl ring substituted with a halogen (i.e., fluoro);

ii. R^1 is hydrogen;

iii. R^5 is an =O group;

iv. R^2 and R^8 - R^{10} are hydrogen.

f. **Ozaki et. al.** (CAS printout XP-002520057 – cited on the IDS): The compounds of *Benzamide, 2-(2-methyl-4-oxo-1(4H)-quinazolinyl)* and *Benzamide, 2-(2-(1-methylethyl)-4-oxo-1(4H)-quinazolinyl)* read on the instant quinazolinone formula with the following substituents as recited in claims 1-3, 18 and 19:

i. A is a phenyl ring substituted with $(CR^iR^j)_rC(O)N(R^{47}R^{48})$;

ii. $r = 0$; R^{47} and R^{48} are hydrogen;

iii. z is a double bond, and R^1 does not exist;

iv. R^5 is a C_{1-6} alkyl group;

v. R^2 and R^8 - R^{10} are hydrogen.

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g. **Moore et. al.** (CAS printout XP-002520060 – cited on the IDS): The compounds of *2,4(1H,3H)-Quinazolinedione, 1-(2-benzoylphenyl)* and *2,4(1H,3H)-Quinazolinedione, 1-(2-benzoylphenyl)-3-methyl* read on the instant quinazolinone formula with the following substituents as recited in claims 1-3, 18 and 19:

- i. A is a phenyl ring substituted with $(CR^iR^j)_rC(O)R^{46}$;
- ii. $r = 0$; R^{46} is an aryl group;
- iii. R^1 is hydrogen or an alkyl group;
- iv. R^5 is an oxo group;
- v. R^2 and R^8 - R^{10} are hydrogen.

h. **Noda et. al.** (CAS printout XP-002520055 -- cited on the IDS): For example, the compound of *4(1H)-Quinazolinone, 7-chloro-2-methyl-1-(3-chlorophenyl)* reads on the instant quinazolinone formula with the following substituents as recited in claims 1-5, 18 and 19:

- i. A is a phenyl ring substituted with a halogen (chloro);
- ii. R^1 does not exist because z is a double bond;
- iii. R^5 is an alkyl group;
- iv. R^8 is a halogen;
- v. R^2 and R^9 - R^{10} are hydrogen.

i. **Ozaki et. al.** (J. Med. Chem., 1985, 28, pp. 568-576 – cited on the IDS): For example, compound #21 reads on the instant quinazolinone formula with the following substituents as recited in claims 1-5, 18 and 19:

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- i. A is a phenyl ring substituted with a halogen (fluoro);
 - ii. R^1 does not exist because z is a double bond;
 - iii. R^5 is an alkyl group;
 - iv. R^2 and R^8 - R^{10} are hydrogen.
- j. **Hisamitsu Pharm. Co.** (GB 1,311,573 – cited on the IDS): For example, on page 2, left column, lines 12-13, the compound of *1-(3'-chlorophenyl)-2,4-(1H, 3H)-quinazolinedione*, and lines 20-21, the compound of *1-(3'-fluorophenyl)-2,4-(1H, 3H)-quinazolinedione* read on the instant quinazolinone formula with the following substituents as recited in claims 1-4, 18 and 19:

- i. A is a phenyl ring substituted with a halogen (chloro or fluoro);
- ii. R^1 is hydrogen and z is a single bond;
- iii. R^5 is an oxo group;
- iv. R^2 and R^8 - R^{10} are hydrogen.

See also other compounds in all the cited references.

Specification

3. The abstract of the disclosure is objected to because of the following reasons:
- a. When “z” is a single bond, then the ring carbon at 2-position has an incomplete valence.
 - b. When “z” is a double bond, and R^1 is absent, and if R^5 is =O, then the ring carbon at the 2-position has an extra valence.

Correction is required. See MPEP § 608.01(b).

References cited on PTO-892

The references cited on PTO-892 bear related compounds. Though they are not addressed herein, applicants are advised to review them for pertinent subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

11-18-09